

## **REMARKS**

### **1. Claim Amendments**

Applicants have amended claim 7 to remove the 2-thienyl from the definition of R1.

Applicants have amended claims 31 and 32 to depend from claim 7.

Applicants have marked claims 1-6, 9, 15 and 16 as being withdrawn.

No new matter is believed to be added by these amendments.

### **2. Lack of Unity Requirement**

In the Office Action mailed February 8, 2007, the Office set forth a lack of unity requirement and required election of one of the following eleven groups:

Group I, claim(s) drawn to compounds, compositions and methods wherein R1 is phenyl and R5 is halo or phenyl containing.

Group II, claim(s) drawn to compounds, compositions and methods wherein R1 is phenyl and R5 is pyridyl containing.

Group III, claim(s) drawn to compounds, compositions and methods wherein R1 is phenyl and R5 is quinoliny containing.

Group IV, claim(s) drawn to compounds, compositions and methods wherein R1 is thienyl and R5 is halo or phenyl containing.

Group V, claim(s) drawn to compounds, compositions and methods wherein R1 is thienyl and R5 is pyridyl containing.

Group VI, claim(s) drawn to compounds, compositions and methods wherein R1 is thienyl and R5 is quinoliny containing.

Group VII, claim(s) drawn to compounds compositions and methods wherein R1 is benzothienyl and R6 is non-het.

Group VIII, claim(s) drawn to compounds, compositions and methods wherein R1 is benzothienyl and R6 is pyridyl containing.

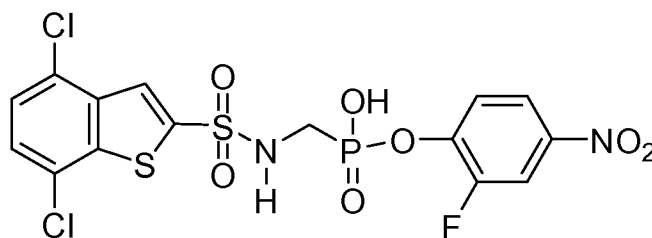
Group IX, claim(s) drawn to compounds, compositions and methods wherein R1 is benzothienyl and R6 is oxazdiazole containing.

Group X, claim(s) drawn to compounds, compositions and methods wherein R1 is benzothienyl and R6 is thienyl.

Group XI, claim(s) drawn to compounds, compositions and methods wherein R1 is benzothienyl and R6 is any other het group other than those above.

Applicants hereby elect group VII, with traverse. Claims 7, 8, 10, 12-14, 17-32 read upon group VII.

The Office also appears to have required an election of species. If this is correct, Applicants hereby elect the species:



This species is compound 248 of Table 2. Claims 7, 8, 10, 12, 18-20, 31 and 32 read upon this species. If Applicants are mistaken and the Office did not require an election of species, please disregard this election.

### **3. Arguments Traversing the Lack of Unity Requirement**

Applicants submit that the Office has improperly grouped the subject matter of the present application. First, the Office improperly separated into different groups compounds for which there exists unity of invention. Second, the Office does not appear to have accounted for all of the subject matter of the application in its groupings.

In view of the comments below, Applicants request that the Office withdraw the unity of invention requirement presented in the Office Action mailed February 8, 2007, and examine together all of the hydrogen (benzo[b]thiophene-2-sulfonamido)methylphosphonate compounds of groups VII-XI.

Because this application entered the national stage under 35 U.S.C. § 371, restriction practice as defined in M.P.E.P Chapter 800 does not strictly apply. Rather, the PCT “unity of invention” standards must be used to determine whether the subject matter of the application is properly divisible. The application must relate to one invention only or to a group of inventions so linked as to form a single general inventive concept as defined under the Patent Cooperation Treaty. M.P.E.P. § 1850. So-called “unity of invention” exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13. When the application claims chemical compounds, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2 shall be considered to be met when the alternatives are of a similar nature, i.e., when the following criteria are fulfilled:

(A) All alternatives have a common property or activity; and

(B)(1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or

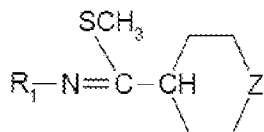
(B)(2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

M.P.E.P. § 1850(III)(B). In paragraph (B)(I), above, the words “significant structural element is shared by all of the alternatives” refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. *Id.*

The final sentence of M.P.E.P. § 1850(III)(B) directs Office personnel to the Examples in Chapter 10 of the International Search and Preliminary Examination Guidelines, available from WIPO at <http://www.wipo.int/pct/en/texts/pdf/ispe.pdf>. Pages 84-88 provide examples for Markush groupings. The example most similar to the Markush groups recited herein is provided below:

10.39 Example 19: common structure:

Claim 1: A compound of the formula:



wherein R<sub>1</sub> is selected from the group consisting of phenyl, pyridyl, thiazolyl, triazinyl, alkylthio, alkoxy, and methyl; Z is selected from the group consisting of oxygen (O), sulfur (S), imino (NH), and methylene (-CH<sub>2</sub>-).

The compounds are alleged to be useful as pharmaceuticals for relieving lower back pain.

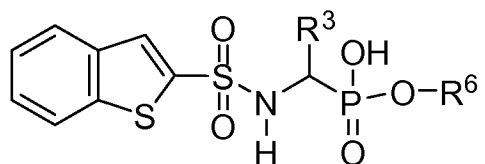
In this particular case the iminothioether group -N=C-SCH<sub>3</sub> linked to a six atom ring is the significant structural element which is shared by all the alternatives. Thus, since all the claimed compounds are alleged to possess the same use, unity would be present.

WIPO, International Search and Preliminary Examination Guidelines, page 85. In this example, unity exists based on the common structural feature of an iminioether group linked to a 6-membered ring. It is important to note that unity exists even though R<sup>1</sup> can be aryl, heteroaryl, or alicyclic.

When making a lack of unity of invention requirement, the Office must (1) list the different groups of claims and (2) explain why each group lacks unity with each other group (i.e., why there is no single general inventive concept) specifically describing the unique special technical feature in each group.

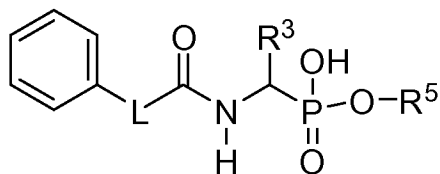
Applicants submit that the Office has not shown that each group lacks unity with each other group. The Office's explanation is limited to asserting only that "there is not a significant structural element, that is a large portion of the molecule or if the common portion is small it must be novel, which is neither the case here; or all the alternatives do not belong to a recognized class of chemical compounds." Office Action mailed February 8, 2007, page 3. Applicants submit that while some groups might lack unity with some others, the listed groups do not all lack unity with all other groups. Rather, there does exist unity between certain of the listed groups.

Most importantly for the elected group, Applicants submit that there is unity of invention between Groups VII-XI. Each compound of these groups has the base structure:



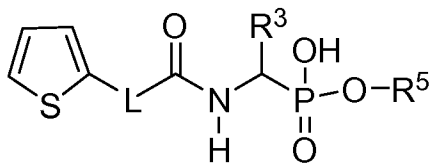
in which the benzothienyl is optionally substituted. Applicants submit that these compounds share a common significant structural element; they are all hydrogen (benzo[b]thiophene-2-sulfonamido)methylphosphonates. Just as in Example 10.39 of the International Guidelines, the fact that R<sup>6</sup> can include different cycloalkyl, aryl or heteroaryl moieties does not destroy this unity. Applicants submit that these compounds share a single general inventive concept.

Applicants further submit that there is unity of invention between Groups I-III. Each of these groups has the base structure:



in which the phenyl is optionally substituted and L is a covalent bond, -CH<sub>2</sub>O-, -C(O)-, or -C(=N-OCH<sub>3</sub>). Applicants submit that these compounds share a common significant structural element; they are all hydrogen (phenyl-terminated amido)methylphosphonates. Just as in Example 10.39 of the International Guidelines, the fact that R<sup>5</sup> can include different cycloalkyl, aryl or heteroaryl moieties does not destroy this unity.

Applicants further submit that there is unity of invention between Groups IV-VI. Each of these groups has the base structure:



in which the thienyl is optionally substituted and L is a covalent bond, -CH<sub>2</sub>O-, -C(O)-, or -C(=N-OCH<sub>3</sub>). Applicants submit that these compounds share a common significant structural element; they are all hydrogen (thienyl-terminated amido)methylphosphonates. Just as in Example 10.39 of the International Guidelines, the fact that R<sup>5</sup> can include different cycloalkyl, aryl or heteroaryl moieties does not destroy this unity.

Applicants note that many of the claims of the present application are in Markush format. Because the subject matter recited by each of these claims has unity of invention, these Markush claims should be fully examined. The proper procedure for examining Markush claims is provided in M.P.E.P. § 803.02:

“An Examiner should set forth a requirement for election of a single disclosed species in a Markush-type claim. . . . Following election, the Markush-type claim will be examined fully with respect to the elected species, and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable, the provisional election will be given effect and examination will be limited to the Markush-type claim and claims to the elected species. . . . On the other hand, should the examiner determine that the elected species is allowable, the examination of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a *nonelected species*, the Markush-type claim shall be rejected and claims to the non-elected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant . . . overcome the rejection [e.g., by amendment] . . . the amended Markush-type claim will be reexamined. The examination will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action can be made final unless the examiner introduces a new ground of rejection that is neither necessitated by applicant’s amendment of the claims nor based on information submitted in an information disclosure statement during the period set forth in 37 C.F.R. 1.97(c) with the fee set forth in 37 C.F.R. 1.17(p).”

The procedure in M.P.E.P. § 803.02 allows the Office to examine a broad Markush-type claim in a stepwise fashion, instead of requiring him to examine the entire scope of the claim at once. Thus, it strikes a balance between the right of the Applicants to have their claims examined fully, and the interest of the Office in streamlining Examiner workflow. The Office must first to examine the claim with respect to the elected species. If no prior art rejections are

made, the examiner must then extend the examination to the “extent necessary to determine patentability.” Accordingly, the Office is to begin searching non-elected species covered by the Markush claim, continuing to search additional species until he finds prior art rendering the claim unpatentable. Once such art is found, the Office may stop the search and reject the claims in an Office Action. The Applicants may then respond, for example by amending the claim or traversing the rejection. If the Applicants overcome the rejections, the Office is to continue searching until more art is found rendering the claims unpatentable. This examination/rejection/response cycle does not necessarily continue until the full scope of the claim is examined; rather, the Office may in certain circumstances make a second or subsequent action final. As such, Markush examination is similar to examination of a regular claim in that Applicants do have an unlimited right to make amendments to obviate prior art rejections.

Applicants note that the Office appears to have required an election of species, and presume that the Office will follow the procedures outlined in M.P.E.P. § 803.02 in examining the claims of the present invention.

Moreover, Applicants submit that the Office does not appear to have accounted for sulfonamide compounds in which R<sup>1</sup> is 2-thienyl (e.g., as recited in claims 7, 9 and 15-17). Applicants submit that, at the very least, these thienyl-substituted sulfonamides should themselves be grouped together in a single group. Of course, they might also properly be grouped together with Groups VII-XI, into a group of hydrogen (thiophene-2-sulfonamido)methylphosphonates.

In sum, Applicants submit that the unity of rejection requirement is improper because Office has failed to group together compounds for which there is unity of invention. Applicants propose that the following grouping of compounds would be more proper:

- I. Hydrogen (phenyl-terminated amido)methylphosphonate compounds. Claims 1-6, R<sup>1</sup> = phenyl. Groups I-III of the Office Action.
- II. Hydrogen (thienyl-terminated amido)methylphosphonate compounds. Claims 1-6, R<sup>1</sup> = thienyl. Groups IV-VI of the Office Action.

III. Hydrogen (benzo[b]thiophene-2-sulfonamido)methylphosphonate compounds  
Claims 7, 8, 10-14, 17-31. Groups VII-XI of the Office Action.

IV. Hydrogen (benzo[b]thiophene-2-sulfonamido)methylphosphonate compounds  
Claims 7 (as originally-presented), 9, 15-17. Not explicitly assigned to groups in  
Office Action.

Accordingly, Applicants request that the Office withdraw the unity of invention  
requirement presented in the Office Action mailed February 8, 2007, and examine together all of  
the hydrogen (benzo[b]thiophene-2-sulfonamido)methylphosphonate compounds of groups VII-  
XI.

Please direct any questions or comments to the undersigned at the telephone number  
provided below.

Respectfully submitted,

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